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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/728,463	10/10/1996	NILS LONBERG	14643-009020	2701

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	33

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/728,463	Lonberg et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication app ars on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 3-16-01 and 5-7-01

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-9, 15-17, and 54-64 is/are pending in the applica

4a) Of the above, claim(s) 1-9 and 15-17 is/are withdrawn from considera

5) ☒ Claim(s) 61 is/are allowed.

6) ☒ Claim(s) 54-60 and 62-64 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: Notice to comply with Sequence Requirements

DETAILED ACTION

1. Applicant's amendment, filed 3-16-01 (Paper No. 25), and applicant's sequence CRF and paper copy of said CRF filed 5-7-01 is acknowledged. Applicant is thanked for sending a duplicate paper copy of said sequences. Applicant is also thanked for sending a courtesy copy of the references for IDS .

2. It is noted that the CRF by itself is in sequence compliance. However it is also noted that the This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, on page 38 of the instant specification, lines 16, 17 and 18 contain 4 sequences which are not identified by a SEQ ID tag. Furthermore, on page 163 of the instant specification, lines 24 and 25 contain 2 sequences which are not identified by a SEQ ID tag. Furthermore on page 254-256, SEQ ID NO:s 1-10 do not agree with SEQ ID NO:s 1-10 of the CRF and paper copy submitted with the CRF.

3. Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 attached to the office action mailed 12-8-1998, (Paper No.14).

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A). Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B) Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the

examiner before the application will be allowed. No changes will be permitted to be made, other than correction of
informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

4. The rejections of record can be found in the previous Office Action, mailed 9-12-00 (Paper No. 26).

In view of applicant's amendment and remarks all outstanding rejections have been withdrawn.

However in view of applicant's newly added claims, new grounds of rejection have been applied.

NEW GROUNDS OF REJECTION

5. A) Applicant is advised that should claim 58 be found allowable, claim 59 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

B) Claims 58-59 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 58-59 do not further limit their base claims because the recited Ka would be an inherent property of the Ig secreted by 10C5 or 4D1. This objection is stated under the assumption that these claims are interpreted as claiming the whole Ig, rather than the heavy chain. See 112, second paragraph rejection further below.

C) Claims 58-60 are objected to for the following informality: Consistency as to whether the instant claims commence with "The" or "A" is required. "The" is preferred.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his

invention.

7. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 55 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "An immunoglobulin having heavy and light chain variable regions encoded by SEQ ID NO:205 and 206". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.** Applicant is invited to point out the exact page which discloses support.

8. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 57 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "An immunoglobulin having heavy and light chain variable regions encoded by SEQ ID NO:207 and 208". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.** Applicant is invited to point out the exact page which discloses support.

9. Claims 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an IgG immunoglobulin comprising CDR1, CDR2 and CDR3 encoded by SEQ ID NO:205 and CDR1, CDR2 and CDR3 encoded by SEQ ID NO:206, and for an IgG immunoglobulin comprising CDR1, CDR2 and CDR3 encoded by SEQ ID NO:207 and CDR1, CDR2 and CDR3 encoded by SEQ ID NO:208,and for an IgG immunoglobulin comprising CDR1, CDR2 and CDR3 encoded by SEQ ID NO:219 and CDR1, CDR2 and CDR3 encoded by SEQ ID NO:220, does not reasonably provide enablement for the broader recitation of an IgG immunoglobulin comprising an immunoglobulin that does not contain all of the recited CDR1, CDR2 and CDR3 regions of both the heavy and a light chain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 62-64 are indefinite in the recitation because it is not clear if each heavy chain is comprised of one, two or all three CDR regions (ie CDR1 and/or CDR2 and/or CDR3). **The following enablement rejection applies ONLY if claims 62-64 are interpreted as not requiring that the heavy and light chains have all three of the three CDRs recited, in the order recited**. The scope of the claims is not

commensurate with the enablement provided by the disclosure with regard to an immunoglobulin comprising heavy and light chain variable regions which encompass any number and/or combination of CDR1, CDR2 and CDR3 regions encoded by SEQ ID NO:205 or SEQ ID NO:206, respectively, as recited by claim 62, nor with regard to the extremely large number of combinations of CDR regions from an immunoglobulin comprising heavy and light chain variable regions which encompass any number and/or combination of CDR1, CDR2 and CDR3 regions encoded by SEQ ID NO:207 or SEQ ID NO:208, respectively, as recited by claim 63, nor with regard to an immunoglobulin comprising heavy and light chain variable regions which encompass any number and/or combination of CDR1, CDR2 and CDR3 regions encoded by SEQ ID NO:219 or SEQ ID NO:220, respectively, as recited by claim 64. Janeway teaches that the association of different heavy and light chain variable regions form the antigen binding site (see page 3:21, last paragraph). Therefore, it is not clear that any combination of CDR regions will have the asserted utility of binding to CD4, without further guidance from the specification. It would require undue experimentation for one of skill to predict which combinations of CDR regions would result in an immunoglobulin with the asserted utility of binding CD4.

In view of the quantity of experimentation necessary to use the claimed invention, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

11. Claims 54-60 and 62-64 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claims 54 and 58-60 are indefinite in their recitation in claim 54 and dependent claims 58-60, of "wherein the immunoglobulin is 10C5" because the it is not clear what "10C5" means, especially since the specification discloses that 10C5 is a hybridoma.

B) Claims 56 and 58-60 are indefinite in their recitation in claim 56 and dependent claims 58-60, of "wherein the immunoglobulin is 4D1" because the it is not clear what "4D1" means, especially since the specification discloses that 4D1 is a hybridoma.

C) Claim 55 is indefinite in its recitation of "An immunoglobulin having heavy and light chain variable regions encoded by SEQ ID NO:205 and 206" because it is not

clear if the heavy variable region is encoded by SEQ ID NO:205 or by SEQ ID NO:206 or both, similarly it is not clear if the light variable region is encoded by SEQ ID NO:205 or by SEQ ID NO:206 or both.

D)Claim 57 is indefinite in its recitation of "An immunoglobulin having heavy and light chain variable regions encoded by SEQ ID NO:207 and 208" because it is not clear if the heavy variable region is encoded by SEQ ID NO:207 or by SEQ ID NO:208 or both, similarly it is not clear if the light variable region is encoded by SEQ ID NO:207 or by SEQ ID NO:208 or both. respectively like claims

E) Claims 62-64 are indefinite in the recitation because it is not clear if each heavy chain is comprised of one, two or all three CDR regions (ie CDR1 and/or CDR2 and/or CDR3). 55 77 and/or

F) Claims 58 and 59 are unclear as to whether they are describing the heavy chain claimed in base claims 54 and 56, or whether they are describing the whole immunoglobulin from which the heavy chain is derived.

12. A) Claim 61 is allowable because the prior art does not teach or suggest an immunoglobulin comprising heavy and light chains variable regions as encoded by the amino acid sequences set forth in SEQ ID NO:219 and SEQ ID NO:220, respectively.

B) Claims 54-60 and 62-64 would be allowable if rewritten or amended to overcome the objections and the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraphs, set forth in this Office action.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600

receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
March 15, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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